

URGENT PRODUCT RECALL NOTIFICATION

September 24, 2016

Re: BioSentry™ Track Sealant System

Product Code: 768022019S

Lot Numbers: MAWX380, MAZR350, MAZD460, MBCF540

Dear Valued Customer:

Surgical Specialties Mexico is voluntarily recalling the above referenced product due to the potential for an open seal on the product package. To date we have received only one customer complaint and no reported injuries. Our investigation has identified the cause of this failure and we have implemented actions to prevent the defect from recurring. The recall is limited to product number 768022019S, lot numbers MAWX380, MAZR350, MAZD460, MBCF540 and was shipped to your facility between March 10, 2016 and July 26, 2016.

Please review your current inventory and segregate the affected lot numbers. To ensure our customers have received this notification and to arrange for replacement product and the return of identified product, please complete the attached Customer Acknowledgment Form and return via fax to our Quality Assurance department at 610.404.4010 or return via e-mail to kknappenberger@surgicalspecialties.com.

We apologize for any inconvenience this may have caused you or your staff. If you have any questions concerning this notification, please contact Kelly Knappenberger at 484.220.2402 or Kris Liberacki at 262.994.8083.

Regards,

Kris Liberacki
Director, QA/RA
Surgical Specialties